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K042344

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

EXCIA TOTAL HIP SYSTEM

February 25, 2005

COMPANY: Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034

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800-258-1946 (phone)
610-791-6882 (fax)
joyce.kilroy@aesculap.com (email)

TRADE NAME: Excia Total Hip System

COMMON NAME: Hip System

DEVICE CLASS: CLASS II

PRODUCT CODE: LWJ, JDI, LZO

CLASSIFICATION: 888.3350, 888.3353

REVIEW PANEL: Orthopedics

INTENDED USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCr and is intended for cemented fixation. The other femoral stem is for uncemented fixation and is manufactured from Ti with a Ti plasma spray.

DEVICE DESCRIPTION

The Excia Total Hip System is available with two femoral designs. One is manufactured from Ti with a Ti plasma spray coating (Plasmapore). This component is intended for uncemented use. The other femoral component design is manufactured from CoCrMo and is intended for cemented use. Distal centralizers maintain the stem's alignment in the femoral canal. The centralizers are manufactured from PMMA.

The acetabular cup (Plasmacup) is manufactured from Ti and is coated with Plasmapore as well. Acetabular cup screws can be used for further cup fixation. The acetabular inserts are UHMWPE and available in symmetrical and asymmetrical designs.

Two femoral heads are available. The CoCrMo heads may be used with either the cemented or cementless femoral stems. However, the ceramic heads are for use only with the Ti alloy cementless stems.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Opposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements"
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Draft Guidance for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the new Excia Total Hip System is substantially equivalent in design to:

- BiCONTACT Hip System (K040191)
- 36mm V40 Femoral Head Components (K022077)
- Alloclassic Zweymueller (K030373)
- SC Total Hip System (K031474)
- Smith & Nephew Hip System (K022902)
- Pinnacle Duofix HA Acetabular Cup (K031495)
- Trident Porous Ti Acetabular Component with Coating (K013475)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Ms. Joyce Kilroy
Director of Regulatory Affairs & Quality Assurance
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K042344

Trade/Device Name: Excia Total Hip System
Regulation Number: 21 CFR 888.3353; 21 CFR 888.3350
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II
Product Code: LZO, JDI, LWJ
Dated: February 25, 2005
Received: February 25, 2005

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

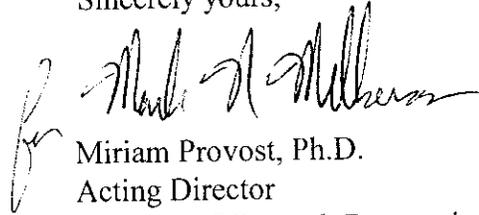
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over a faint, larger signature that is partially obscured.

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042344

Device Name: Excia Total Hip System

Indication for Use:

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
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Prescription Use X or Over-the-Counter Use _____
(per 21 CFR 801.109)


(Division Sign-Off)

Division of General, Restorative,
and Neuro

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K042344